IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP., Plaintiff, v. BOSTON SCIENTIFIC CORP. and BOSTON SCIENTIFIC NEUROMODULATION CORP., Defendants.	Civil Action No. 21-258-CFC

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MEMORANDUM OPINION

December 20, 2021
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

Plaintiff Nevro Corp. has sued Defendants Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. (collective BSC) for infringement of U.S. Patent Nos. 10,556,112 (the #112 patent); 10,576,286 (the #286 patent); 8,892,209 (the #209 patent); 8,792,988 (the #988 patent); and 9,333,357 (the #357 patent). D.I. 1 at 1. Pending before me is BSC's motion to dismiss. D.I. 10. BSC argues I should dismiss Nevro's complaint because the asserted patents are invalid under 35 U.S.C. § 101 for failing to claim patentable subject matter.

I. BACKGROUND

This motion to dismiss comes before me in the most recent of many intellectual property suits between BSC and Nevro. *See Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 25 (Fed. Cir. 2020); *Bos. Sci Corp. v. Nevro*, No. 16-1163; *Bos. Sci Corp. v. Nevro*, No. 18-0644. BSC and Nevro are medical device manufacturers that develop and sell spinal cord stimulation (SCS) systems for the treatment of chronic pain. D.I. 1 ¶¶ 6–7. SCS systems reduce pain by delivering electrical pulses to the spinal cord. D.I. 1 ¶ 2. Previously SCS systems produced a sensation known as paresthesia—which is often described as tingling, numbness, or pins-and-needles. D.I. 1 ¶ 3. Nevro introduced SCS systems that reduce pain without paresthesia. D.I. 1 ¶ 5.

The asserted patents claim systems and methods for paresthesia-free pain relief using SCS systems. Nevro alleges that BSC infringes at least claim 1 of each asserted patent. D.I. 1 ¶¶ 28, 45, 63, 80, 98. Claim 1 of the #286 patent recites

> [a] method for reducing or eliminating pain in a patient, without causing paresthesia in the patient, the method comprising:
>
> programming a computer-readable medium of an implanted signal generator to:
>
> generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1.2 kHz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 20 mA; and
>
> transmit the therapy signal to the dorsal column of the patient's spinal cord via a signal delivery device implanted in the patient's epidural space and electrically coupled to the implanted signal generator.

Claim 1 of the #112 patent recites

> [a] spinal cord stimulation system for reducing or eliminating pain in a patient, the system comprising:
>
> an implantable signal generator that, in operation, generates a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal is at a frequency of from 500 Hz to 1,200 Hz, with a pulse width in a pulse width range from 10 microseconds to 50 microseconds, and a current amplitude in a current amplitude range from 0.5 mA to 7 mA; and
>
> a signal delivery device electrically coupled to the implantable signal generator to deliver the therapy signal to the dorsal column of the patient's spinal cord.

Claim 1 of the #357 patent recites

> [a] spinal cord modulation system for delivering an electrical therapy signal to a patient's spinal cord, wherein the system is configured to deliver the electrical therapy signal to the patient's spinal cord via one or more implantable signal delivery devices, the system comprising:
>
> a signal generator coupleable to the one or more signal delivery devices and having executable instructions to generate and deliver the electrical therapy signal to the patient's spinal cord from an epidural location via the one or more signal delivery devices,
>
> wherein the electrical therapy signal has
>
> a plurality of sequential bi-phasic pulses having a pulse width between 10 microseconds and 333 microseconds, and
>
> an amplitude between 0.5 mA and 10 mA, which at least partially reduces the patient's sensation of pain without generating paresthesia.

Claim 1 of the #988 patent recites

> [a] method for programming a signal generator to deliver a therapy signal to a patient']s spinal cord via at least one implantable signal delivery device, wherein the implantable signal delivery device is positioned to deliver the therapy signal to the patient's spinal cord at a vertebral level between T9 and T12, inclusively, the method comprising:
>
> configuring the signal generator to generate a therapy signal, wherein the therapy signal is a plurality of bi-phasic pulses having a pulse width between 25 microseconds and 166 microseconds; and
>
> programming the signal generator to deliver the therapy signal at a frequency and amplitude that at least partially reduces the patient's sensation of pain without generating paresthesia.

Claim 1 of the #209 patent recites

> [a] spinal cord modulation system for reducing or eliminating pain in a patient, the system comprising:
> a pulse generator configured to generate a non-paresthesia producing therapy signal, wherein the therapy signal includes a plurality, of sequential bi-phasic pulses with pulse widths between 10 microseconds to 333 microseconds; and
> an implantable signal delivery device electrically coupled to the pulse generator and configured to.

II. LEGAL STANDARDS

A. Stating a Cognizable Claim

To state a claim on which relief can be granted, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Detailed factual allegations are not required, but the complaint must include more than mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). The complaint must set forth enough facts, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). Deciding whether a claim is plausible is a "context-specific task that

requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679 (citation omitted).

When assessing the merits of a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and it must view those facts in the light most favorable to the plaintiff. *See Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008); *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (internal quotation marks omitted).

B. Patent-Eligible Subject Matter

Section 101 of the Patent Act defines patent-eligible subject matter: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

There are three judicially-created limitations on the literal words of § 101. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). These exceptions to patentable subject matter arise from the concern that the monopolization of "these basic tools of scientific and technological work" "might tend to impede innovation more than it would tend to promote it." *Id.* (internal quotation marks and citations omitted).

"[A]n invention is not rendered ineligible for patent [protection] simply because it involves [ineligible subject-matter]." *Alice*, 573 U.S. at 217. "[A]pplication[s] of such [subject matter] to a new and useful end . . . remain eligible for patent protection." *Id.* (internal quotation marks and citations omitted). But in order "to transform an unpatentable law of nature [or abstract idea] into a patent-eligible application of such law [or abstract idea], one must do more than simply state the law of nature [or abstract idea] while adding the words 'apply it.'" *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012) (emphasis omitted).

In *Alice*, the Supreme Court established a two-step framework by which courts are to distinguish patents that claim eligible subject matter under § 101 from patents that do not claim eligible subject matter under § 101. The court must first determine whether the patent's claims are drawn to a patent-ineligible concept—i.e., are the claims directed to a law of nature, natural phenomenon, or abstract idea? *Alice*, 573 U.S. at 217. If the answer to this question is no, then the patent is not invalid for teaching ineligible subject matter. If the answer to this question is yes, then the court must proceed to step two, where it considers "the elements of each claim both individually and as an ordered combination" to determine if there is an "inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a

patent upon the [ineligible concept] itself." *Id.* at 217–18 (alteration in original) (internal quotations and citations omitted).

Issued patents are presumed to be valid, but this presumption is rebuttable. *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 96 (2011). Subject-matter eligibility is a matter of law, but the party challenging a patent's validity must show underlying facts by clear and convincing evidence. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).

III. DISCUSSION

A. Representative Claims

BSC identifies claim 1 of each patent as representative. D.I. 11 at 13 n.7, 18 n.10. Nevro does not respond. Accordingly, I adopt claim 1 of each patent as representative. In addition, neither party argues that any of the patents present distinct questions at step one of the *Alice* test, and, therefore, the parties implicitly accept that all asserted patents are directed to the same subject matter.

B. *Alice* Step One—Whether the Claims Are Drawn to Patent-Ineligible Subject Matter

I begin with the first step of the *Alice* framework and determine if the claims at issue are directed to a patent-ineligible concept. *Alice*, 573 U.S. at 217. "Laws of nature and natural phenomena are not patentable, but applications and uses of such laws and phenomena may be patentable." *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d 1319, 1324 (Fed. Cir. 2020), *cert. dismissed*, 141 S. Ct.

2171 (2021). The Federal Circuit has consistently found methods of treatment patents subject-matter eligible—even when the claims do not require medical devices. *See, e.g.*, *Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1344 (Fed. Cir. 2019) ("[C]laims that are directed to particular methods of treatment are patent eligible."); *Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 919 F.3d 1347, 1353 (Fed. Cir. 2019); *see also Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 967 F.3d at 1325 ("[W]e have held that method of treatment claims are patent-eligible.").

The asserted patent claims, when considered as a whole, are directed to systems and methods for treatment that incorporate a natural phenomenon, not the natural phenomenon itself. Each patent requires an "implantable signal generator" or "implantable signal delivery device." #286 patent at claim 1 (14:63); #112 patent at claim 1 (15:8); #357 patent at claim 1 (25:66–67); #988 patent at claim 1 (25:64–65); #209 patent at claim 1 (25:54). Each patent further requires that the signal delivery devices are configured to generate therapeutic electrical pulses within specified parameter ranges. #286 patent at claim 1 (14:64–15:2); #112 patent at claim 1 (15:8–14); #357 patent at claim 1 (26:6–12); #988 patent at claim 1 (26:1–4); #209 patent at claim 1 (25:49–53). And each patent specifies that the claimed methods and systems must deliver or be configured to deliver the electrical pulses to the patient's spinal cord. #286 patent at claim 1 (15:3–5); #112

patent at claim 1 (15:15–17); #357 patent at claim 1 (25:63–66); #988 patent at claim 1 (25:65–67); #209 patent at claim 1 (25:54–56). These additional claim elements are much more than window dressing for a natural phenomenon. The Federal Circuit has repeatedly explained that there is a difference between applying a natural phenomenon to a useful end and claiming the natural phenomenon itself. For example, the Federal Circuit has found that a claim teaching the manufacture of "a human dietary supplement with certain characteristics" was subject-matter eligible, because the "supplement is not a product of nature and the use of the supplement to achieve a given result is not directed to a law of natures." *Nat. Alternatives*, 918 F.3d at 1350. Similarly, an SCS system is not a natural phenomenon, and neither is the use of such systems to "achieve a given result," such as paresthesia-free pain relief. The systems and methods claimed in the asserted patents are subject-matter eligible inventions for the useful purpose of treating chronic pain. They are not subject matter ineligible because they happen to incorporate a natural phenomenon in realizing that purpose.

BSC argues that to identify what a patent is directed to I must look to the "focus of the claimed advance over the prior art." D.I. 11 at 11 (citing *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332, 1338 (Fed. Cir. 2017)). According to BSC, this approach reveals that the asserted claims are "directed to the natural phenomenon of paresthesia-free therapy with conventional instructions

to apply it." D.I. 11 at 13. BSC argues that paresthesia-free therapy is the distinguishing feature of the asserted patents, and that, therefore, the patents are directed to paresthesia-free therapy. D.I. 11 at 14. Since paresthesia-free pain relief is a natural physiological reaction that occurs in response to certain electrical pulses, the patents, according to BSC, are directed to patent-ineligible subject matter. D.I. 11 at 15.

BSC's analysis, however, fails to consider the asserted claims as a whole. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 750 (Fed. Cir. 2019) ("The step one 'directed to' inquiry focuses on the claim as a whole."), *cert. denied*, 140 S. Ct. 855 (2020); *see also Diamond v. Diehr*, 450 U.S. 175, 188 (1981). It is true that identifying the "focus of the claimed advance" of a patent can help identify whether that patent is directed to an abstract idea, and the Federal Circuit recognizes the utility of this approach. *Intellectual Ventures I*, 850 F.3d at 1338 ("Under the abstract idea step we evaluate the focus of the claimed advance over the prior art to determine if the claim's character as a whole is directed to excluded subject matter." (internal quotation marks and citation omitted)). But BSC stretches this methodology past its breaking point. The *Alice* inquiry does not myopically focus on a claim's novel features when the claim as a

whole suggests a different focus.[1] *See Mayo*, 566 U.S. at 71 ("[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm."); *Endo Pharms.*, 919 F.3d at 1353 ("[A]t step one, it is not enough to merely identify a patent-ineligible concept underlying the claim.").

Here the claims as a whole are directed to systems and methods for treatment using SCS systems. They extend beyond the idea of paresthesia-free treatment itself, as they require specialized medical devices, particular signal properties, and the delivery of electrical pulses to a patient's spinal cord. *See, e.g.*, #286 patent at claim 1. The fact that they incorporate natural phenomena is of no moment. Medicinal treatment necessarily relies on physiological phenomena and that fact does not render all method of treatment patents invalid under § 101. *See Nat. Alternatives*, 918 F.3d at 1345 (recognizing that methods of treatment necessarily rely on the human body's physiological responses).

BSC reliance on *Mayo* and *INO Therapeutics LLC v. Praxair Distribution, Inc.*, 782 F. App'x 1001 (Fed. Cir. 2019) is unavailing. The patent in *Mayo* identified only the relationship between certain metabolites and safe dosages of a

[1] BSC strongly suggests that the asserted patents are either anticipated by or obvious over the Oakley reference. *See* D.I. 11 at 9–10; *see also* D.I. 12, Ex E (Oakley reference). But § 101 and § 102 (and § 103) impose distinct requirements for eligibility, and it would be improper to rule on § 102 (or § 103) under the guise of § 101.

drug; it did not offer an inventive method of treatment. 566 U.S. at 77. And in *INO* the asserted claim simply identified a group of patients that experienced adverse results when given iNO gas to treat hypoxic respiratory failure. 782 F. App'x at 1005. Here, in contrast, the asserted claims are directed to systems and methods for treatment that go beyond simply identifying a physiological reaction.

BSC is careful to not suggest that SCS technology in general is ineligible for patent protection. Indeed, in parallel litigation BSC is accusing Nevro's SCS system of infringing numerous BSC patents on SCS technology. *See Bos. Sci. Corp.*, No. 16-1163. Agreeing with BSC on the present motion would require a conclusion that when an otherwise patentable invention incorporates a natural phenomenon as part of an additional claim limitation, the invention is no longer eligible for patent protection. But "[a] claim to otherwise statutory subject matter does not become ineligible by its use of a law of nature or natural phenomenon." *Illumina*, 967 F.3d at 1324. The asserted claims here are directed to methods of treatment that invoke a natural phenomenon, not to that natural phenomenon itself. The claims are, therefore, not invalid under § 101.

C. *Alice* Step Two—Whether the Claims Contain an Inventive Concept

Because I find the asserted patents directed to eligible subject matter at step one of the *Alice* test, I need not, and do not, consider step two. *See Alice*, 573 U.S. at 218.

IV. CONCLUSION

For the reasons stated above, I find the asserted patents not invalid under § 101. Accordingly, I will deny BSC's motion to Dismiss. D.I. 10.

The Court will issue Orders consistent with this Memorandum Opinion.